



Docket No. FDA-2018-N-3805 for “Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.”

December 14, 2018

The opioid crisis has damaged the health and longevity of our nation as a whole, and will have impacts beyond the generations of today. We hope the outcomes of the information you weigh today and in other relevant areas will result in saved lives, a decrease of the economic burdens on our nation, and reduced stigma for the millions affected by opioid and substance use disorders.

S.A.F.E. Project is a relatively young non-profit (just a year old) created in the memory of Jonathan Winnefeld, who died in his college dorm room in 2017, at the age of 19. He did not want to die, but he had a disease and the life saving medication, naloxone, was not given to him. If it had, he could continue pursuing his dreams - dreams of living without drugs, and dreams of helping others.

Earlier this year, S.A.F.E. launched a pilot program that we call the Naloxone Awareness Project. With the help of staff and volunteers, we visited pharmacies around Virginia, a state with some of the broadest access laws for dispensing naloxone under a standing order. What we found surprised us.

We thought we would find overt stigma to be the most common barrier to naloxone access. It was not. In fact, not one person who did this project was asked by a pharmacist or pharmacy technician why they were requesting naloxone, and no visitor reported feeling disrespected for asking.

However, only 70% of our visitors were actually offered the option of purchasing naloxone upon request. The most common barrier to naloxone in this exercise was a lack of knowledge of the ability to provide naloxone to patients. This was true despite the existence of Virginia’s standing order. Nearly all of the smaller independent pharmacies had difficulty understanding the situations in which they could provide naloxone without a prescription. Smaller pharmacies often did not have naloxone at all, and would require 24 hours to order it and receive it.

If pharmacies in Virginia relatively close to Washington, DC are not informed well enough to dispense naloxone to customers that request it, we will never successfully address this problem. Larger chains were more likely to carry naloxone and have an awareness of the standing order, but many of those larger chains have mandated or provided training across their retail sites.

Communities that have stepped up access to naloxone are watching opioid deaths decrease. A revived person has another chance at recovery, parenting, caring for other loved ones, a career, a purpose, and success. No person should die of an overdose when someone, anyone, with naloxone could have saved them, but for lack of awareness or access did not.

The Surgeon General has called for naloxone in every first aid kit. We hope you will find a way to give naloxone the place it deserves - in the hands of those who are willing to help.

Additionally, there is no reason why naloxone should be behind the counter. Restricted placement inspires unfounded fear and concern for both the person looking to potentially save a loved one's life, and those behind the counter.

We also have concern that making it over the counter without appropriate market competition or price control will not provide the increased access desired. Naloxone must remain affordable, with or without insurance.

Finally, we believe every prescribed opioid should come with a label with information about naloxone. A side effect of opioids is respiratory depression, which can be deadly. Taking a pill without food or milk usually isn't, but there tends to be a label telling the patient how to better care for themselves while taking that medication.

Thank you for your time and consideration of this important issue.